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120

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/226,895    01/07/99    ROSENBLUM    M    D6205

HM22/1207  
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EXAMINER

CANELLA, K

ART UNIT	PAPER NUMBER
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1642  
DATE MAILED:

12/07/00

**Please find below and/or attached an Office communication concerning this application or proceeding.**

**Commissioner of Patents and Trademarks**

# Office Action Summary

Application No.  
09/226,895

Applicant(s)  
Rosenblum et al

Examiner  
Karen Canella

Group Art Unit  
1642



- ☐ Responsive to communication(s) filed on \_\_\_\_\_
- ☐ This action is **FINAL**.
- ☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

## Disposition of Claim

- ☒ Claim(s) 1, 5-9, and 11 is/are pending in the application.
- Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- ☒ Claim(s) 1, 5-9, and 11 is/are rejected.
- ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- ☐ Claims \_\_\_\_\_ are subject to restriction or election requirement.

## Application Papers

- ☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.
- ☐ The drawing(s) filed on \_\_\_\_\_ is/are objected to by the Examiner.
- ☐ The proposed drawing correction, filed on \_\_\_\_\_ is ☐ approved ☐ disapproved.
- ☐ The specification is objected to by the Examiner.
- ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. § 119

- ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- ☐ All ☐ Some\* ☒ None of the CERTIFIED copies of the priority documents have been
- ☐ received.
- ☐ received in Application No. (Series Code/Serial Number) \_\_\_\_\_.
- ☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

\*Certified copies not received: \_\_\_\_\_

- ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

## Attachment(s)

- ☒ Notice of References Cited, PTO-892
- ☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). \_\_\_\_\_
- ☐ Interview Summary, PTO-413
- ☐ Notice of Draftsperson's Patent Drawing Review, PTO-948
- ☐ Notice of Informal Patent Application, PTO-152

— SEE OFFICE ACTION ON THE FOLLOWING PAGES —

***Response to Amendment***

1. Claims 2, 3, 4 and 10 have been canceled. Claims 1, 5 and 7 have been amended. Claims 1, 5-9 and 11 are under consideration.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

***New Claim Rejections***

3. Claims 1, 7-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al (Proceedings of the American Association for Cancer Research, 1997, Vol. 38, p. 88) in view of Flavell et al (Cancer Research, 1997, Vol. 57, pp. 4824-4829). The instant claims are drawn in part to a method of treating an individual having leukemia or lymphoma comprising the administration of a retinoid to upregulate the CD38 antigen and the administration of an anti-CD38 antibody conjugated to gelonin, wherein said antibody-gelonin conjugate is administered in a dose from 0.05 mg/kg to 2 mg/kg. Mehta teaches a method of killing leukemia cells in culture comprising the administration of retinoic acid to upregulate the expression of the CD38 antigen, followed by the administration of a antibody-gelonin conjugate specific for the upregulated CD38 antigen. Mehta does not teach a method of treating an individual having leukemia or lymphoma. Flavell teaches a method of treating a mouse carrying human B-cell lymphoma comprising the administration of a anti-CD38-saporin conjugate in a dose which lies within the claimed range. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to treat an individual having leukemia or lymphoma by the administration of retinoic acid followed by an anti-CD38 gelonin conjugate. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teachings of Flavell et al on the efficacious use of the anti-CD38 saporin conjugate in vivo.

4. Claims 1, 5-9 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Mehta et al, 1997 and Flavell et al as applied to claims 1, 7-9 and 11 above, and further in view of Mehta et al (Proceeding of the American society for Cancer Research, 1994, Vol. 35, p. 92).

Claims 5 and 6 are drawn in part to all-*trans* retinoic acid and dosage of 0.1 mg/kg to 2 mg/kg of said retinoid. Mehta et al, 1997 do not teach all-*trans* retinoic acid or a dose of said all-*trans* retinoic acid. Mehta et al, 1994 teach a method of treating individuals having acute promyelocytic leukemia comprising the administration of all-*trans* retinoic acid in a dose of 45 mg/m<sup>2</sup> which lies within the range of claim 6. It would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to use all-*trans*-retinoic acid in dose of 45 mg/m<sup>2</sup>. One of ordinary skill in the art would have been motivated to do so with a reasonable expectation of success by the teaching of Mehta et al, 1994, on the significant increase of CD38 expression observed in vivo following a single oral dose of all-*trans*-retinoic acid.

5. All other rejections and objections as recited in Paper No. 3 are withdrawn.

### *Conclusion*

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Canella whose telephone number is (703) 308-8362. The examiner can normally be reached on Monday through Friday from 8:30 am to 6:00 pm. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anthony Caputa, can be reached on (703) 308-3995. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0196.



ANTHONY C. CAPUTA  
UNITED STATES PATENT EXAMINER

Karen A. Canella, Ph.D.

Patent Examiner, Group 1642

December 3, 2000